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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/864,373	05/25/2001	William F. Krise	KRISE 1A	1608

7590 06/03/2003

Office of Counsel Code OC4  
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[REDACTED] EXAMINER

PADMANABHAN, KARTIC

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1641

DATE MAILED: 06/03/2003

4

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/864,373	KRISE ET AL.
	Examiner Kartic Padmanabhan	Art Unit 1641

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 24 March 2003.

2a) This action is FINAL.                            2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-14 is/are pending in the application.

4a) Of the above claim(s) 1-6 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 7-14 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) 1-14 are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 18 June 2002 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.

4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of Group II in Paper No. 7 is acknowledged.

### ***Information Disclosure Statement***

2. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

### ***Specification***

3. The disclosure is objected to because of the following informalities: On page 8, applicant has attempted to replace (NIMRA) with Near Infrared Molecular Assay (NIRMA). However, the examiner advises that applicant make a formal amendment to this effect to avoid printer confusion should the application pass to issue at some future time.

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 11-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 11 is rejected as vague and indefinite for the recitation of a “tip” because it is unclear to what applicant is referring with this term. A “tip” is generally thought of as a pointed end of something or a small piece serving as the end of something. However, it is unclear how this definition fits in with the claim. In addition, the limitation of an “enclosed target area” is also vague and indefinite because it is unclear if applicant means this term to mean surrounded, covered, or completely sealed off from the rest of the apparatus.

7. Claim 12 is rejected as vague and indefinite for the recitation of a “tip” and “enclosed” for reasons discussed with respect to claim 11. Further, the limitation of a tip free of solid phase is unclear because isn’t the tip itself a solid phase?

8. Claim 13 is rejected as vague and indefinite for the recitation of “adapted” because it has been held that the recitation that an element is “adapted to” perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138.

9. Claim 14 recites the limitation “the diameter” in line 2 of the claim. There is insufficient antecedent basis for this limitation in the claim.

#### ***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 7-9 and 12-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Izmailov (US Pat. 6,397,150 B1). The reference discloses an apparatus for sequencing DNA, which comprises a light source (excitation source) in the form of laser diodes. Fiber optic lenses collect emitted light and pass it through filters. The apparatus also comprises secondary bandpass filters to exclude certain wavelengths of light from the detectors. Photodetectors adjacent to the filters detect light transmitted by the filters. The presence of a sample holder is inherent because sample is irradiated in the reference, and the sample has to be held by something for this to occur. Anything that holds or contains sample qualifies as a sample holder. Further since the meaning of tip and free of solid phase of claim 12 is too vague to adequately interpret, the configuration of the reference, wherein a sample is irradiated on an open surface, is sufficient to meet this claim limitation. In addition, since the recitation of the device being adapted to hold an eel of claim 13 does not constitute a limitation in any patentable sense (See paragraph 8 above), the claim is also anticipated by the reference as it does not further limit the claim on which it depends.

12. Claims 7-9 and 12-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Wang et al. (US Pat. 5804,451). The reference discloses an optical system, wherein a laser diode may be used as the light source. The apparatus may also comprise a bandpass filter as the filter means, as well as a fiber optic lens. A single channel or multi-channel detector may also be employed with the reference. The presence of a sample holder is inherent because sample is irradiated in the reference, and the sample has to be held by something for this to occur. Anything that holds or contains sample qualifies as a sample holder. Further since the meaning of tip and free of solid phase of claim 12 is too vague to adequately interpret, the configuration

of the reference, wherein a sample is irradiated on an open surface, is sufficient to meet this claim limitation. In addition, since the recitation of the device being adapted to hold an eel of claim 13 does not constitute a limitation in any patentable sense (See paragraph 8 above), the claim is also anticipated by the reference as it does not further limit the claim on which it depends.

13. Claims 7 and 9-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Giebelter et al. (US Pat. 6,236,456 B1). The reference discloses an optical system comprising a light source which may be a lamp or laser. The light passes through a filter wheel comprising a plurality of filters, which filters may be bandpass filters. The sample holder of the reference may be a cuvette or a multi-assay plate well. In the event of a multi-well plate, the plate as a whole is interpreted as the sample holder, and the individual wells are tubes which reduce the diameter of the sample holder. Although mirrors are preferred, the device of the reference may also comprise a fiber optic lens. In one embodiment, the detector of the reference may be a photodiode. The device may also include an LCD readout. Further, since the meanings of claims 11 and 12 are too vague to adequately interpret, when the target analysis area enters the reading chamber via the housing door, the enclosed analysis area limitation of claim 11 is deemed met. Before entry into this reading area, the sample holder that is not enclosed of claim 12 is deemed met. In addition, since the recitation of the device being adapted to hold an eel of claim 13 does not constitute a limitation in any patentable sense (See paragraph 8 above), the claim is also anticipated by the reference as it does not further limit the claim on which it depends.

***Conclusion***

Claims 7-14 are rejected.

Reference: Ivarsson et al. is cited as art of interest for teaching an optical biosensor system.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kartic Padmanabhan whose telephone number is 703-305-0509. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-5207 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Kartic Padmanabhan  
Patent Examiner  
Art Unit 1641

\*\*\* *KP*  
June 1, 2003

*Long Le*  
LONG V. LE  
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06/02/03